



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,020	03/16/2001	Robert Charles Downs	P0037US00	9097

29490 7590 03/19/2003

TIMOTHY L. SMITH  
GENOMICS INSTITUTE OF THE  
NOVARTIS RESEARCH FOUNDATION  
10675 JOHN JAY HOPKINS DRIVE, SUITE E225  
SAN DIEGO, CA 92121-1127

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT PAPER NUMBER

1651

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/810,020

Applicant(s)

DOWNS, ROBERT CHARLES

Examiner

Dr. Kailash C. Srivastava

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/24/2002 as Paper Number 8.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The assigned Examiner to your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1651.
2. Applicant's response filed December 24, 2002 as Paper Number 8 in response to Office Action mailed on September 18, 2002 as Paper number 7 is acknowledged and entered.
3. Claims 32-58 are cancelled.
4. Claims 1-31 are pending.

### ***Election/Restriction***

5. Applicant's election without traverse of Group I, Claims 1-31 filed on December 24, 2002 as Paper Number 8 to election requirement in Office Action mailed on September 18, 2002 as Paper number 7 is acknowledged and entered. Further review in this application shows that a restriction is required as outlined below.
6. Restriction to one of the following inventions is required under 35 U.S.C. 121:  
  
Group I – Claims 1-15 and 23-25 drawn to a method of fermentation to make a product, classified under Class 435, Subclass 71.1, for example.  
  
Group II – Claims 16-20 drawn to another method, classified under Class 435, Subclass 41 for example.  
  
Group III – Claims 21-22 drawn to a robotic assay method, classified under Class 901, subclass 1 or 6 for example.  
  
Group IV – Claims 26-31 drawn to a method of protein crystallization and X-ray crystallography, classified under Class 435, subclass 4 for example.
7. The processes/methods in Groups I-IV are unrelated to each other because they are directed to inventions that are not connected in design, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. The inventions have different modes of operation, they have different functions, and/or they

have different effects. One would not have to practice the various inventions at the same time to practice just one invention alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for e. g., inventions disclosed in Groups I-III are different from each other because each one of these inventions has different steps, require different components and are drawn to identify a different material. For e.g., inventions in Groups I or III will not be practiced together because one is a method of making a product and other a method to test the properties of the product made. Similarly inventions in Groups III and IV will not be practiced simultaneously because the invention in group III does not require X-ray crystallography.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (class/subclass) and their recognized diverse subject matter, restriction for examination purposes as indicated is proper.

### **Species Election**

8. This application contains claims directed to methods comprised of a variety of components. Therefore, if the applicant elects any of Groups as cited above, the applicant must also make election of species by electing at least one single species from each of the following categories:

A. Wherein the Fermentation Process encompasses:

- a. attaching a fermenter head to the sample vessels;
- b. attaching a robotic gripper apparatus;

B. Wherein the fermentation process comprises cells or particles containing:

- a. prokaryotic cells;
- a. gene fragment in a vector;

- b. gene variant in a vector;
  - b. eukaryotic cells;
    - a. gene fragment in a vector;
    - b. gene variant in a vector;
  - c. virus particles;
    - a. gene fragment in a vector;
    - b. gene variant in a vector;
- C. Wherein the Fermentation Process also encompasses:
  - a. aerobic fermentation;
  - b. anaerobic fermentation;
- D. Wherein, the further processing step is none other than one among the following:
  - a. centrifuging the fermented samples in the sample vessel that was used for fermentation;
  - b. aspirating the sample;
  - c. sonicating the sample;
  - d. washing the sample;
  - e. agitating the sample;
  - f. lysing cells in the fermented sample;
  - g. isolating a product from the fermented sample;
    - Column chromatography;
- E. Wherein, method employs the further processing steps:
  - a. a robot tests tens to thousands of variants of a protein;
  - b. robot includes a plate handler;
- F. Crystallizing the isolated product from the fermented sample:
  - a. analyzing by X-ray crystallography;
  - b. identifying crystals using crystal algorithms;
  - c. crystals are frozen and analyzed by X-ray diffraction.

If applicant elects the invention in group I, applicant must elect at least one single species from each of the following categories:

Aa or Ab;

Ba or Bb or Bc (i.e., either Baa, Bab, Bba, Bbb, Bca or Bcb);

Ca or Cb; and

Da, Db, Dc, Dd, De, Df, or Dg.

If applicant elects the invention in group II, applicant must elect at least one single species from each of the following categories:

Ea or Eb and Fa, Fb or Fc.

An example of responsive election of invention and election of species to the above stated election requirement will be for e.g., "applicant elects to prosecute invention in Group I, claims 1-15 and 23-25 and further makes the species election as follows:

Aa, Bba, Ca and Dg.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

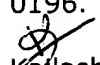
In accordance with 37 CFR 1.499, applicant is also required that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species [MPEP § 809.02(a)].

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention and species, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1651  
(703) 605-1196

March 17, 2003



CHRISTOPHER R. TATE  
PRIMARY EXAMINER